(12) UK Patent Application (19) GB (11) 2 385 533 (13) A

(43) Date of A Publication 27.08.2003

(21) Application No 0300371.2

(22) Date of Filing 08.01.2003

(30) Priority Data
(31) 0204161 (32) 22.02.2002 (33) GB

(71) Applicant(s)
Smiths Group Plc
(Incorporated in the United Kingdom)
765 Finchley Road, LONDON, NW11 8DS,
United Kingdom

(72) Inventor(s)
Andrew James Lee
Giles Andrew Bishop

(74) Agent and/or Address for Service
J M Flint
765 Finchley Road, LONDON, NW11 8DS,
United Kingdom

(51) INT CL[7]
A62B 18/02

(52) UK CL (Edition V)
A5T TCL

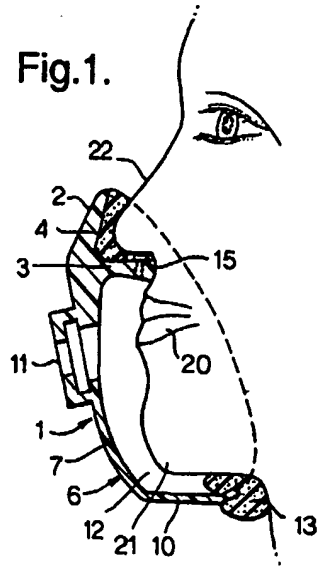
(56) Documents Cited
GB 2368800 A
EP 0634196 A2
DE 004004157 C
US 5243972 A

(58) Field of Search
UK CL (Edition V) A5T TCE TCF TCH TCL
INT CL[7] A62B 18/02
Other: Online: EPODOC, JAPIO, WPI

(54) Abstract Title
Face mask with seal around nose

(57) A face mask has a shell 1 of a foamed material with a peripheral sealing edge 13 extending around the mouth. The mask also includes a shelf 3 with a conformable material 25, which may seal the nostrils closed or seal them with two spigots 24 providing gas passages into the interior of the shell. A one-piece elastic strap 50 holds the mask to the face.

Fig.1.



GB 2 385 533 A

Fig.1.

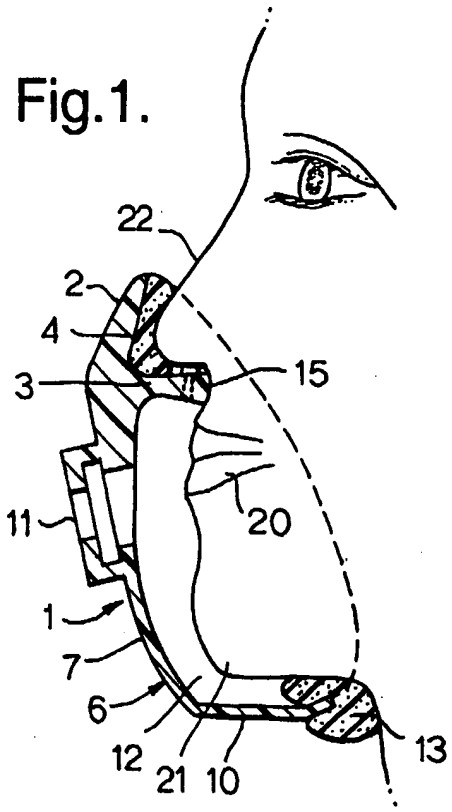


Fig.2.

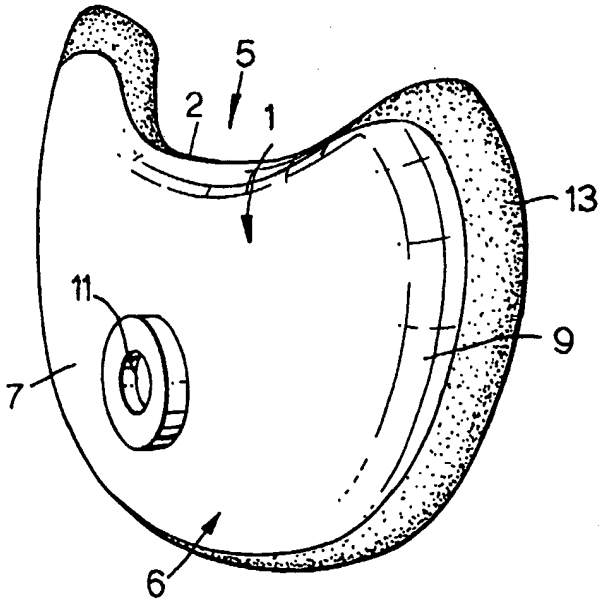


Fig.3.

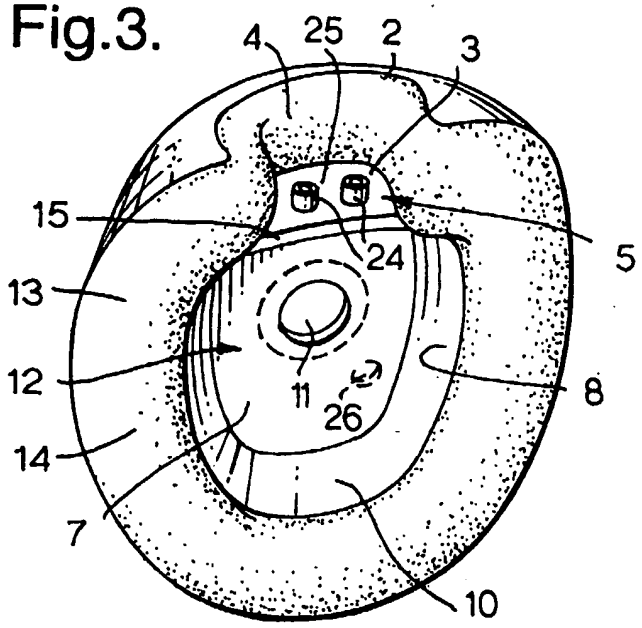


Fig.4.

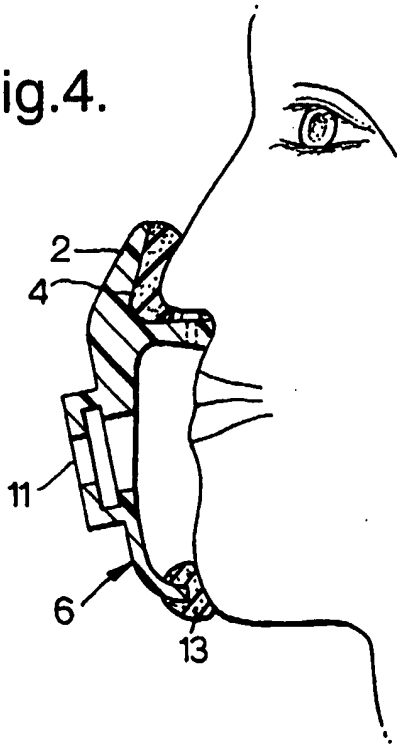


Fig.5.

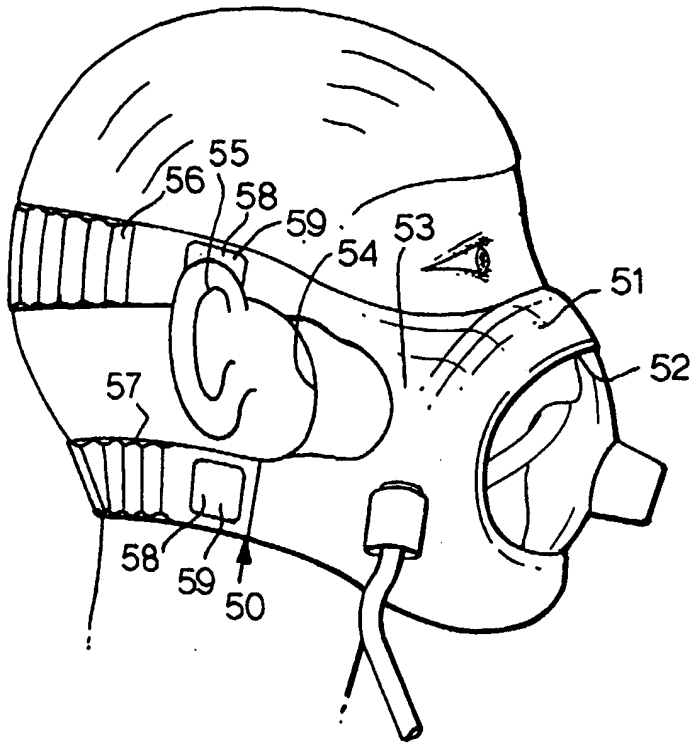


Fig.6.

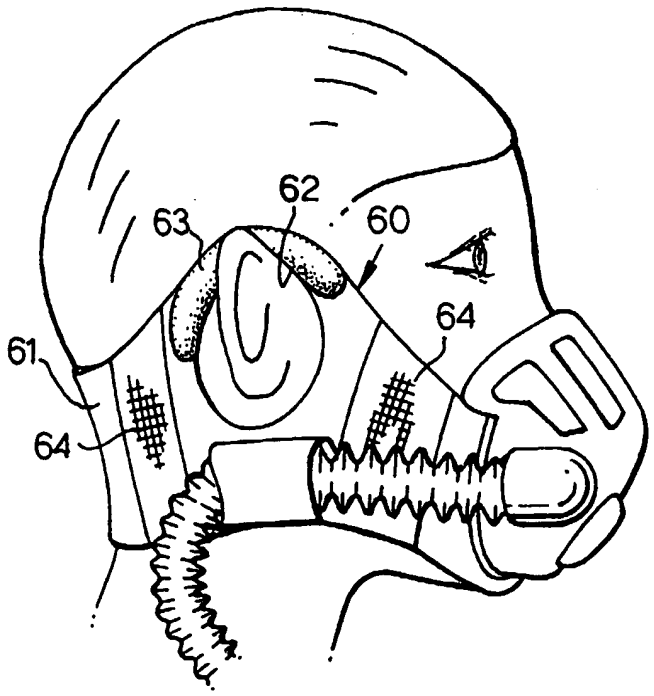


Fig.7.

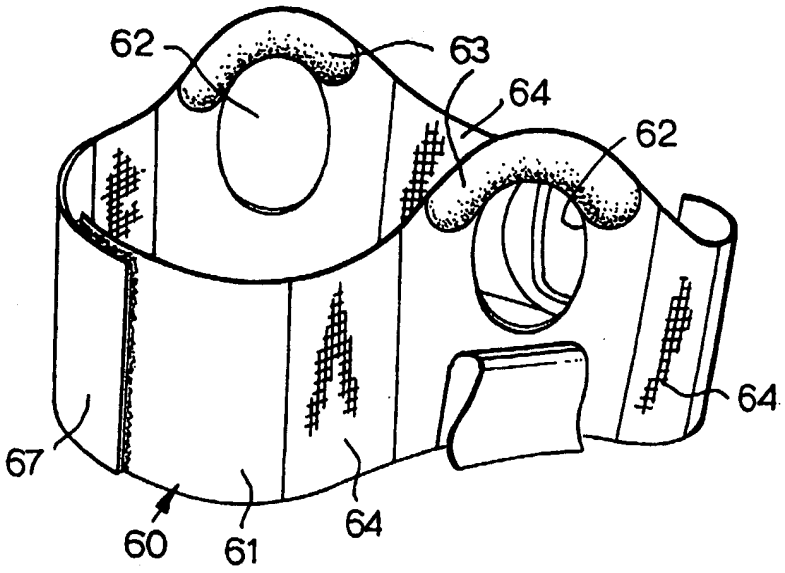


Fig.8.

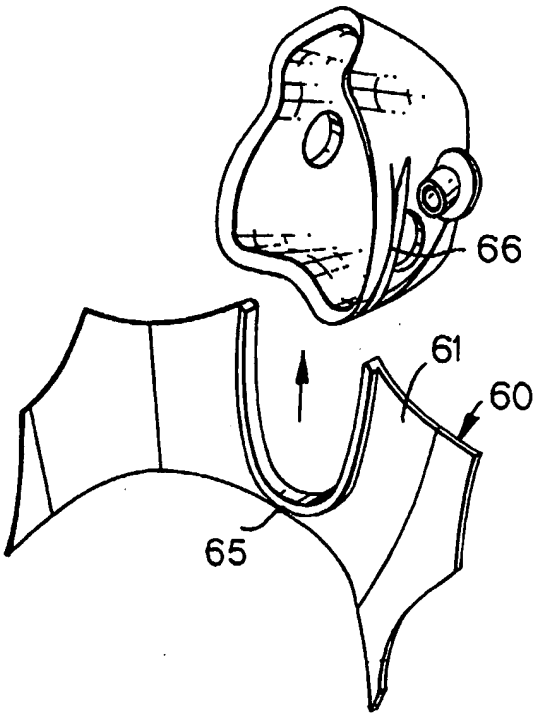


Fig.9.

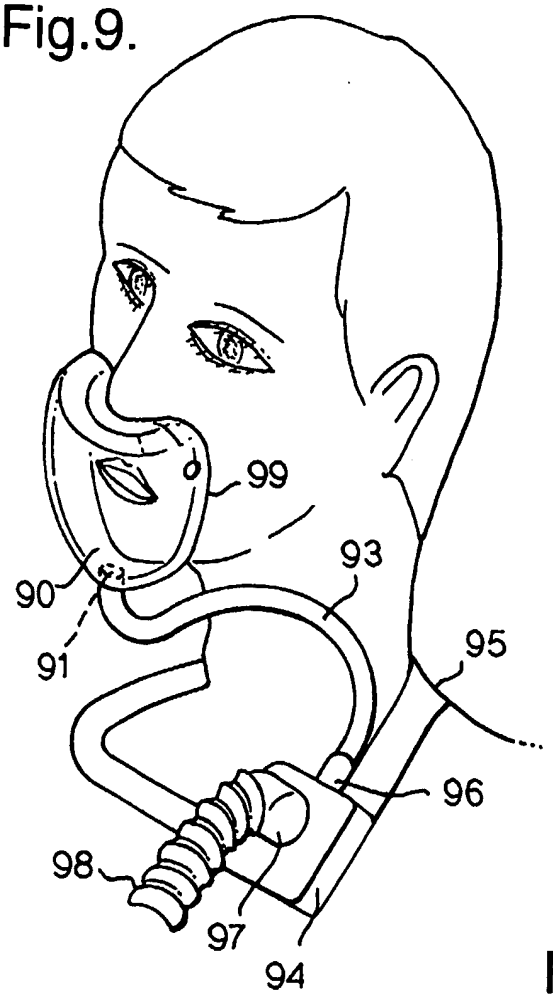
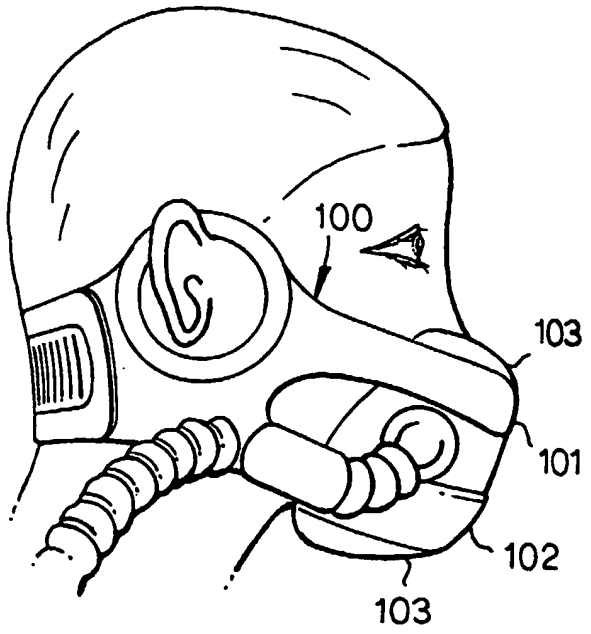


Fig.10.



MASK APPARATUS

This invention relates to mask apparatus.

Masks are used to supply air or other gas to a patient via his mouth, nose or both. Masks take many different forms but the most common comprises a semi-rigid domed shell shaped to fit around the periphery of both the nose and mouth. The shell usually has some form of softer material around its edge, which provides a seal with the skin surface. An opening in the mask includes a coupling by which the mask is connected to ventilation or anaesthesia equipment. The shell is usually retained in position by means of straps extending around the rear of the patient's head and adjustably fastened to opposite sides of the shell.

There are various problems with existing masks. One problem is that of achieving an effective seal with the contours of the face. Although it is not essential to provide a completely gas-tight seal with the skin surface, if there is not a good fit, gas escaping between the mask and skin can cause discomfort to the patient. Attempts to increase the seal by tightening the straps can increase pressure on the face, which also causes discomfort. Another problem with masks that enclose the nose is that some patients find them claustrophobic. Also, they often prevent the patient wearing spectacles. The straps used to hold the mask on the head can often be difficult to position and adjust correctly.

One important use of breathing masks is in CPAP (continuous positive airway pressure) or BIPAP (bi-directional positive airway pressure) ventilation for relieving sleep

apnoea, where the mask is worn at home while asleep. It is particularly important for such masks to be easy to use and comfortable.

A further problem arises from the gas feed tube connected with the mask because the weight or force applied to this often applies a force tending to separate the mask from the face, which needs to be overcome by tightening of the straps.

It is an object of the present invention to provide alternative mask apparatus.

According to the present invention there is provided mask apparatus including a domed shell having a peripheral sealing edge shaped to contact the skin surface around the mouth and between the mouth and nose, the shell having a shelf formation on its upper external surface adapted to locate adjacent the nostrils of the nose and to seal around the nostrils.

The shelf formation may include a gas passage communicating with the interior of the shell and adapted to communicate with the nostrils of the nose such that gas supplied to the shell also flows to the nose. The gas passage may be provided by two spigots arranged to enter respective nostrils, the spigots being surrounded by a conformable material to prevent escape of gas between the spigots and the nostrils. Alternatively, the shelf formation may be provided with means arranged to seal the nostrils closed. The mask may include a conformable material above the shelf adapted to contact the lower end of the nose and prevent passage of gas therethrough. The mask is preferably of a foamed plastics material. The peripheral sealing edge may be selected from a group comprising: a soft foam, a gel-

filled member and an adhesive. The mask apparatus preferably includes a strap member, the strap member being a one-piece construction of an elastic material. The strap member may have an opening adapted to receive the mask shell, the strap member being arranged to extend around the sides of the head above and below the ears. The strap member may have a U-shape opening into which the mask shell is slid. The mask apparatus may include a flexible, relatively small bore tube connected at one end with and opening into the mask shell and connected at its opposite end with a coupling adapted to receive a second, relatively large bore tube, the coupling being adapted for mounting adjacent the patient such that the weight of the larger bore tube is substantially isolated from the mask shell by the coupling. The coupling is preferably adapted to be secured on the patient's body

Various forms of mask apparatus according to the present invention will now be described, by way of example, with reference to the accompanying drawings, in which:

Figure 1 is a cross-sectional side elevation view of a mask;

Figure 2 is a perspective view of the front of the mask;

Figure 3 is a perspective view of the rear of the mask;

Figure 4 is a cross-sectional side elevation view of a modified form of mask;

Figure 5 is a side elevation view of a strap arrangement;

Figure 6 is a side elevation view of a modification of the strap arrangement in Figure 5 worn by the patient;

Figure 7 is a perspective view of the strap arrangement of Figure 6 off the patient;

Figure 8 is a perspective view of a part of the strap arrangement of Figures 6 and 7;

Figure 9 is a perspective view of an alternative mask arrangement employing a remote gas feed tube; and

Figure 10 is a side elevation view of a modified form of the strap arrangement of Figures 6 to 8.

With reference first to Figures 1 to 3, the mask has a domed shell 1 of a semi-rigid, impervious foamed plastics material. At its upper end, the shell 1 has a shallow part-circular wall 2 extending around a horizontal shelf 3, which forms the floor of a recess 4 in the upper end of the mask. The recess 4 opens at its rear side via a gap 5. The lower part 6 of the shell is generally circular when viewed from the front, having a front wall 7 and two side walls 8 and 9 extending generally vertically, and a lower surface 10 extending generally horizontally. A connector or coupling (not shown) is fitted in an opening 11 through the front wall 7 and opens into the interior cavity 12 of the lower part 6. The cavity 12 is open around the rear of

the shell 6 and its edge is bordered by a seal member 13. The seal member 13 may be of various different kinds, such as a soft foam or a gel-filled tube, which are soft or deformable and conform to the contours of the face. The seal 13 has a relatively wide portion 14 of horse-shoe shape extending along the periphery of the side walls 8 and 9 and the lower surface 10. The seal 13 also has a narrower portion 15 extending as a bar along the rear edge of the shelf 3.

The shape of the lower part 6 of the shell is such that it encloses the mouth 20 and chin 21 of the patient without substantially enclosing the nose 22. The seal member 13 extends and seals with the skin surface under the chin 21 and along the cheeks on either side of the mouth 20, with the bar portion 15 engaging the skin between the mouth and the nose.

The recess 4 is adapted to seal around the nostrils of the nose 22. The mask may be arranged to supply gas either to just the mouth 20 or to both the mouth and the nose 22. Where the mask is to supply gas to the nose 22 as well as the mouth 20, the shelf 3 has two short spigots 24 located to enter respective nostrils. The spigots 24 are surrounded by a soft conformable material 25, such as a foam, a bean-bag like pillow, a gel or a similar material to help seal around the nostrils and prevent escape of gas between the spigots and the nostrils. Where the mask is to supply gas to just the mouth 20, the shelf 3 is preferably imperforate without any gas passage through it and the conformable material in the recess 4 is arranged to contact and seal closed the lower end of the nose 22, preventing passage of gas into or out of the nose.

The shell 1 preferably also has a small opening 26, shown in broken outline, through which a nasogastric tube (not shown) can pass. The opening 26 opens into the cavity 12 of the mask, the nasogastric tube passing from this cavity into the nasal passage via one of the spigots 24. A removable plug (not shown) is inserted in the opening 26 to close it when not in use.

Instead of the lower end of the mask extending under the chin, it may contact and seal with the lower part of the face just above the chin, as shown in Figure 4.

The shell 1 may be held against the face by conventional straps secured to fixings (not shown) on the shell. Alternatively, the shell may be held in place by alternative strap means shown in Figure 5. This Figure shows the strap means used on a different form of mask shell from that described above but it will be appreciated that similar strap means can be used with the shell shown in Figures 1 to 4 with very little modification. The strap means of the arrangement shown in Figure 5 is indicated generally by the number 50. It is made of a soft, highly flexible, elastic, breathable fabric material such as similar to that used in the construction of babies' nappies or diapers. The strap arrangement 50 is a one-piece construction having a forward region 51, which is generally rectangular in section with a central opening 52 of circular shape. Opposite sides 53 of the central region 51 are cutaway to form curved recesses 54 to receive the patient's ears 55. Upper and lower straps 56 and 57 extend from one side of the forward region 51 and are terminated with hook/loop fasteners 58 adapted to attach to hook/loop fasteners 59 on the opposite side of the central region. In use, the strap arrangement 50 completely encircles the head, with the shell of the mask located in the opening 52 and the forward region 51 overlapping the shell slightly at its upper edge and

at its lower edge where it extends under the chin. The upper and lower straps 56 and 57 extend around the back of the head above and below the ears, being secured at the fasteners 58 and 59. This strap arrangement 50 can be easily fitted either before or after the mask shell is placed in position over the mouth.

Figures 6 to 8 show a similar strap arrangement 60 extending completely around the head. In this arrangement, the strap 60 is in the form of a web 61 of substantially constant width along its length. The web 61 has holes 62 to receive the ears, which may have padded regions 63 above the ears, for comfort. The web 61 is a continuous loop and is rendered highly extensible to accommodate different size patients by several sections of highly elastic material 64. The mask shell is retained by a U-shape semi-rigid section 65 in the strap arrangement, which is received in slots 66 in the mask shell. Again, this enables the mask shell to be fitted before or after the strap arrangement and can provide a compact, comfortable fit. Opposite ends of the web 61 are attached together at the back of the head by mean of hook and loop fasteners 67. There are various ways in which this type of strap arrangement could be modified, such as, for example shown in Figure 10, in which the web 100 is divided into an upper and lower strap 101 and 102 at the front, which extend across the mask shell in two shallow grooves 103 formed in its surface.

With reference now to Figure 9 there is shown a further alternative mask arrangement having a mask shell 90 of similar shape to that in Figures 1 to 4. The gas inlet 91 is located on the lower surface of the shell so that it is directed generally downwardly. A small bore gas supply tube 93 is attached at its upper, downstream end to the inlet 91, the tube typically having an internal diameter of about 10mm and having a smooth, uncorrugated surface. The

tube 93 is of a soft, flexible plastics material so that it can flex readily without applying pressure to the mask shell 90. The lower, upstream end of the tube 93 is connected to a coupling 94, which is supported on the patient's body. Preferably the coupling 94 is secured on the body adjacent the mask shell 90, such as by means of a collar 95 extending around the patient's neck. The coupling 94 has an outlet port 96 on an upper edge to which the small bore tube 93 is connected. The outlet port 96 communicates via a passage in the coupling 94 with an inlet port 97 on a front surface of the coupling. A conventional larger diameter, corrugated gas feed tube 98 is connected to the inlet coupling. This arrangement isolates the mask shell 90 from the weight and any force applied to the gas feed tube 98 so that the mask shell is only subject to the weight and forces applied by the small bore tube 93, which are considerably less. Because of the reduced force applied to the mask shell 90 it may be possible to support it on the face solely by means of an adhesive 99 around the sealing edge of the mask, without the need for any strap arrangement. The mask could, however, be used with conventional straps. The small bore tube also has the advantage that it provides less obstruction in the head region and enables freer head movement.

CLAIMS

1. Mask apparatus including a domed shell having a peripheral sealing edge shaped to contact the skin surface around the mouth and between the mouth and nose, wherein the shell has a shelf formation on its upper external surface adapted to locate adjacent the nostrils of the nose and to seal around the nostrils.

2. Mask apparatus according to Claim 1, wherein the shelf formation includes a gas passage communicating with the interior of the shell and adapted to communicate with the nostrils of the nose such that gas supplied to the shell also flows to the nose.

3. Mask apparatus according to Claim 2, wherein the gas passage is provided by two spigots arranged to enter respective nostrils, and wherein the spigots are surrounded by a conformable material to prevent escape of gas between the spigots and the nostrils.

4. Mask apparatus according to Claim 1, wherein the shelf formation is provided with means arranged to seal the nostrils closed.

5. Mask apparatus according to Claim 4, wherein the mask includes a conformable material above the shelf adapted to contact the lower end of the nose and prevent passage of gas therethrough.

6. Mask apparatus according to any one of the preceding claims, wherein the mask is of a foamed plastics material.

7. Mask apparatus according to any one of the preceding claims, wherein the peripheral sealing edge is selected from a group comprising: a soft foam, a gel-filled member and an adhesive.

8. Mask apparatus according to any one of the preceding claims, including a strap member, wherein the strap member is a one-piece construction of an elastic material.

9. Mask apparatus according to Claim 8, wherein the strap member has an opening adapted to receive the mask shell and wherein the strap member is arranged to extend around the sides of the head above and below the ears.

10. Mask apparatus according to Claim 8 or 9, wherein the strap member has a U-shape opening into which the mask shell is slid.

11. Mask apparatus according to any one of the preceding claims, including a flexible, relatively small bore tube connected at one end with and opening into the mask shell and connected at its opposite end with a coupling adapted to receive a second, relatively large bore tube, wherein the coupling is adapted for mounting adjacent the patient such that the weight of the larger bore tube is substantially isolated from the mask shell by the coupling.

12. Mask apparatus according to Claim 11, wherein the coupling is adapted to be secured on the patient's body.

13. Mask apparatus substantially as hereinbefore described with reference to Figures 1 to 4 of the accompanying drawings.

14. Mask apparatus substantially as hereinbefore described with reference to Figures 1 to 4 as modified by any one of Figures 5 to 8 or Figure 10 of the accompanying drawings.

15. Mask apparatus substantially as hereinbefore described with reference to Figures 1 to 4 as modified by Figure 9 of the accompanying drawings.

16. Any novel and inventive feature or combination of features as hereinbefore described.

Application No:	GB 0300371.2	**Examiner:**	Matthew Parker
Claims searched:	1 to 16	**Date of search:**	29 May 2003

Patents Act 1977 : Search Report under Section 17

Documents considered to be relevant:

Category	Relevant to claims	Identity of document and passage or figure of particular relevance	
X	1,6-12	GB 2368800	(SMITHS), see Figure 2
X	1,6-12	EP 0634186 A2	(RESCARE), see Figure 2
X	1,6-12	DE 4004157 C	(DRAEGERWERK), see Figure 1
X	1,6-12	US 5243972	(HUANG), see Figure 2

Categories:

X	Document indicating lack of novelty or inventive step	A	Document indicating technological background and/or state of the art.
Y	Document indicating lack of inventive step if combined with one or more other documents of same category.	P	Document published on or after the declared priority date but before the filing date of this invention.
&	Member of the same patent family	E	Patent document published on or after, but with priority date earlier than, the filing date of this application.

Field of Search:

Search of GB, EP, WO & US patent documents classified in the following areas of the UKC[V]:

A5T

Worldwide search of patent documents classified in the following areas of the IPC[7]:

A62B

The following online and other databases have been used in the preparation of this search report:

Online: EPODOC, JAPIO, WPI